510(k) Summary

1.0 SUBMITTER INFORMATION

JAN -9 2008

1.1 Submitter:

SHIMADZU MEDICAL SYSTEMS

20101 South Vermont Ave. Torrance, CA 90502-1328

PH: 310-217-8855 FX: 310-217-8869

1.2 Contact:

Don Karle

1.3 Date:

April 25, 2007

2.0 DEVICE NAME

2.1 Proprietary Name:

SDU-2200Pro

2.2 Common Name:

Ultrasound Imaging System

2.3 Classification:

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550, Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560, Product Code 90-IYO Diagnostic Ultrasound Transducer

FR # 892.1570, Product Code 90-ITX

2.4 Predicate Device:

Shimadzu SDU-2200Pro (K061637, Jul./25/06)

3.0 DEVICE DESCRIPTION

The SDU-2200Pro is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Continuous Doppler mode, Color mode, Real time 3D mode, or in a combination of modes.

4.0 INTENDED USE

The SDU-2200Pro is intended for the following applications:

K071287 pg.20f2

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

5.0 SAFETY CONSIDERATIONS

SDU-2200Pro has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- UL60601-1:2003 Medical Electrical Equipment Part I : General Requirements for Safety
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JAN - 9 2008

Mr. Don Karle Manager, Customer Service Shimadzu Medical Systems USA 20101 South Vermont Avenue TORRANCE CA 90502

Re: K071287

Trade/Device Name: Diagnostic Ultrasound System SDU-2200Pro, system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 18, 2007 Received: December 19, 2007

Dear Mr. Karle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Diagnostic Ultrasound System SDU-2200Pro, system, as described in your premarket notification:

Transducer Model Number

<u>L040-075U</u>	<u>VA13R-035U</u>	<u>VA40R-035VNU</u>	<u>EC10R-065VPU</u>
L040-120U	<u>VA13R-050U</u>	<u>VA57R-0375WU</u>	<u>S011-050U</u>
L040-120HU	<u>VA20R-035U</u>	<u>VA57R-0375HU</u>	S017-035U
L070-075U	<u>VA40R-035U</u>	<u>TV11R-055U</u>	S020-025U
<u>L072-050U</u>	<u>VA40R-035HU</u>	<u>UB10R-065U</u>	
<u>VA11R-055U</u>	<u>VA40R-035VPU</u>	EC11R-055U	•

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Ultrasound Device Indications Statement

Page 1 of 23.

510(k) Number (if known):

K071287

Device Name: Diagnostic Ultrasound System SDU-2200Pro, system

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

			,			of Opera	ion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	ļ						1.				
Fetal	<u> </u>	P	P	P		P	P	P	P	P	N
Abdominal		P	P	P		P	P	P	P	P	N
Intra-operative (Specify)							,	·			
Intra-operative Neurological									-		
Pediatric							 				
Small Organ (Specify) *		P	Р	Р		P	Р	P	Р	P	
Neonatal Cephalic											
Adult Cephalic							 		 		<u> </u>
Cardiac	1	P	Р	Р		P	P	P	P	P	
Transesophageal									<u> </u>	<u> </u>	
Transrectal		Р	P	P		P	P	P	P	P.	N
Transvaginal		P	Р	P	-	P	P	P	P	P	N
Transurethral									 		14
Intravascular									-		
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic				-							
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:		
* Thyroid, Testicles, Breast		
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)		
*** Real time 3D		
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(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

07/287

Ultrasound Device Indications Statement Page 2 of 23.

510(k) Number (if known):

Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, L040-075U</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mode	of Opera	ion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmoni c Imaging	Other (Specify) ***
Ophthalmic					:			· · · · · ·		1,11481778	
Fetal	1		T							<u> </u>	
Abdominal									<u> </u>		· · · · · · · · · · · · · · · · · · ·
Intra-operative (Specify)											
Intra-operative Neurological										<u> </u>	
Pediatric				1							
Small Organ (Specify) *		P	P	P		P	P	P	P	P	
Neonatal Cephalic										·	
Adult Cephalic			·			-					
Cardiac			T						-		
Transesophageal				i							
Transrectal											
Transvaginal	: .	-					· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	1	<u> </u>	
Transurethral		-		_			1				
Intravascular								. :			
Peripheral Vascular		P	P	P		P	P	P	P	, P	
Laparoscopic	·				· · ·			7.1			
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Other (Specify)	1.7		7					70.00		N1 + 2 - 1	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Thyroid, Testicles, Brea	st					
* B/M, B/PWD, CFM(B)/PWD, CFM(B)/	CFM(M)			···· /	
** Real time 3D				······		
						·
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number _

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Ultrasound Device Indications Statement Page 3 of 23.

510(k) Number (if known): KUILAX |
Device Name: Diagnostic Ultrasound System SDU-2200Pro, L040-120U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

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Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	_	<u></u>									
Fetal										-	
Abdominal							3				
Intra-operative (Specify)								·.··.		- 	
Intra-operative Neurological											
Pediatric							7-				
Small Organ (Specify) *		Р	Р	P		P	P	P	P	P	
Neonatal								 -			
Cephalic											
Adult Cephalic						· · · · · ·					
Cardiac									 		
Transesophageal								,,	 		<u> </u>
Transrectal								·			
Transvaginal					1						
Transurethral	v					· · · · · · · · · · · · · · · · · · ·					
Intravascular							· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	 		
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic										<u> </u>	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Others (Specify)	,										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

* Thyroid, Testicles, Breast		
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)		· · · · · · · · · · · · · · · · · · ·
*** Real time 3D	<u> </u>	1 1 1 1 1 1 1 1 1
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

Ultrasound Device Indications Statement

Page 4 of 23.

510(k) Number (if known):

K071287

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L040-120HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

						le of Opera	ation		<u> </u>	<u> </u>	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic		 	<u> </u>						T		
Fetal		<u> </u>	<u> </u>								
Abdominal	<u> </u>		<u> </u>								
Intra-operative (Specify)								· · · · · · · · · · · · · · · · · · ·			,
Intra-operative Neurological						··· <u>·</u>					
Pediatric		Γ									
Small Organ (Specify) *		P	P	P		P	P	P	P	P	
Neonatal Cephalic								· 	<u> </u>		
Adult Cephalic								<u> </u>	<u> </u>		
Cardiac									 		
Transesophageal								<u> </u>	-		
Transrectal								· · · · · · · · · · · · · · · · · · ·	-		
Transvaginal								<u> </u>	- 		
Transurethral						· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·			
Intravascular									· 		
Peripheral Vascular		Р	P	P		P	P	P	P	P	
Laparoscopic						- 11 <u>12</u> -	7		 	1	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Others (Specify)									 	 	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Thyroid, Testicles, Breast		-
* B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)		
** Real time 3D		
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

K071287

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Ultrasound Device Indications Statement

Page <u>5</u> of <u>23</u>.

510(k) Number (if known):

K07128

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L070-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic									 	magng	
Fetal						,-			 		
Abdominal									-		
Intra-operative			1						 	· · · · · · · · · · · · · · · · · · ·	ļ .
(Specify)		L.							1 :		
Intra-operative								•	 		
Neurological			l ,								i
Pediatric									 		
Small Organ		D	<u></u>				<u> </u>		 -		
(Specify) *	Ĺ	P	P	P		P	P	P	P	P	
Neonatal									 		
Cephalic		ĺ		i							
Adult Cephalic									 		
Cardiac									 		
Transesophageal		7							 		 -
Transrectal											 -
Transvaginal						3			 	·	
Transurethral										·	
Intravascular	7.0			·					 		ļ
Peripheral Vascular		P	P	P		P	P	P	P		
Laparoscopic	7.1					*	-	F	r	P	
Musculo-skeletal		P	P	P			P	P	 		
Conventional		_		. ^			F	r	P	P	
Musculo-skeletal	\neg	P	P	P		P	P	P	 		<u> </u>
S u perficial		-	-	-		•		r	P	P	
Others (Specify)									 	<u> </u>	

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

*** Real time 3D

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

K071287

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Ultrasound Device Indications Statement Page 6 of 23.

510(k) Number (if known) : _____ K07128

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L072-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

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Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal		L.								· · · · · · · · · · · · · · · · · · ·	
Abdominal											
Intra-operative (Specify)											1
Intra-operative Neurological											
Pediatric							· · · · · · · · · · · · · · · · · · ·				
Small Organ (Specify) *		P	P	P		P	Р	P	P	P	
Neonatal											··
Cephalic											
Adult Cephalic											
Cardiac							<u> </u>				
Transesophageal											
Transrectal							-	·	<u>".</u> .		
Transvaginal									,	··	
Transurethral									100	·	
Intravascular								-		* * * * * * * * * * * * * * * * * * *	<u> </u>
Peripheral Vascular		P	P	P			P	P	P	P	<u> </u>
Laparoscopic							*	. <u>*</u>	1	Р	
Musculo-skeletal		P	P	P		P	P	P	P	P	
Conventional				-				ı.	F	Г	
Musculo-skeletal Superficial									<u> </u>	·	
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
*** Real time 3D	
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Ultrasound Device Indications Statement Page 7

nent Page <u>7</u> of <u>23</u>.

510(k) Number (if known):

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation Clinical Application A В М PWD CWDColorPower Color Combined Tissue Other Doppler (Amplitude) Velocity (Specify) *** (Specify) ** Harmonic Doppler Imaging Imaging Ophthalmic Fetal P P P P P P P P Abdominal P Р P P P P P Intra-operative (Specify) Intra-operative Neurological Pediatric P P P P P P P P Small Organ (Specify) * Neonatal P P P P P P P P CephalicAdult Cephalic P P P P P P P P Cardiac Ρ P Ρ P P P P Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

K071287

Prescription	Use	(Per 21	CFR	801.	.109)
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Ultrasound Device Indications Statement

Page 8 of 23.

510(k) Number (if known): _____

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA13R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mo	le of Opera	ition				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	<u>L</u>		<u>L</u>							<u> </u>	
Fetal		P	P	P	:	P	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative (Specify)										-	
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *		·		, - ''							
Neonatal Cephalic					_					<u> </u>	
Adult Cephalic								,		***	
Cardiac		Р	P	P		P	P	P	P	P	
Transesophageal			·							* 1 ***	
Transrectal	· ·								-		
Transvaginal			,						-		
Transurethral										<u> </u>	
Intravascular							-				
Peripheral Vascular											
Laparoscopic							T				
Musculo-skeletal							-	<u> </u>			
Conventional											
Musculo-skeletal								····		`	
Superficial											1
Others (Specify)									<u> </u>		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:			
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)			
*** Real time 3D			
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Division of Reproductive, Abdominal and

Radiological Devices

Prescription	Use	(Per 2	1 CFR	801	109
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Ultrasound Device Indications Statement

Page 9 of 23.

510(k) Number (if known):

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA13R-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mod	le of Opera	ition				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	Р	Р	
Abdominal]	P	P	P		P	P	Р	Р	P	
Intra-operative (Specify)		i		. "						7	
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic										<u>`</u>	
Cardiac		P	P	P		P	P	P	P	P	
Transesophageal							 	·· <u> </u>			
Transrectal											
Transvaginal							 		:		
Transurethral	i -				· · ·	-				<u> </u>	
Intravascular						· · · · · · · · ·	 		 	<u> </u>	<u> </u>
Peripheral Vascular							· · · · · · · · · · · · · · · · · · ·				
Laparoscopic											
Musculo-skeletal						· ·		7-			 -
Conventional											
Musculo-skeletal Superficial										<u> </u>	
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
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Concurrence of CDRH, Office of Device Evaluation (ODE)	<u> </u>

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number .

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Ultrasound Device Indications Statement Page 10 of 23.

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA20R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

			,			le of Opera	ition				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological									·		
Pediatric	<u> </u>									<u> </u>	
Small Organ (Specify) *				- - -							
Neonatal									 	··	
Cephalic											
Adult Cephalic											
Cardiac		P	P	P		Р	P	P	P	P	
Transesophageal											
Transrectal						·					
Transvaginal									<u> </u>		
Transurethral						· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·		·	
Intravascular						·			<u> </u>		
Peripheral Vascular									 		· · · · · · · · · · · · · · · · · · ·
Laparoscopic								<u> </u>			
Musculo-skeletal						<u> </u>		· · · · · ·	-		
Conventional							ľ				
Musculo-skeletal Superficial								· · · · · · · · · · · · · · · · · · ·			
Others (Specify)						· · · · · · · · · · · · · · · · · · ·					<u> </u>

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	<u> </u>
*** Real time 3D	-
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	<u> </u>
Concurrence of CDRH, Office of Device Evaluation (ODE)	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number _

(07128-

Prescription Use (F											
Ultra	soui	nd I)evi	ce Ind	ication	s Statem	ent Page	e <u>11 </u>	of <u>23</u> .		
510(k) Number (if	lem avv	. /		KG	1128	7					
Device Name : <u>Dia</u>			Iltras	2 bruios	vetem S	Dilanna	ro VAAND ()25TI			
		<u> </u>	<i>7</i> 1 61 646	outra D	Y SCOTT C	DU-22001	10, VA401 <u>\</u> -(<u>1330</u>			
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	agnos	stic u	ıltrasou	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:	
						de of Opera			•		
Clinical	A	В	М	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
Application						Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify) **	Harmonic	(Specify)
Ophthalmic							Doppler	imaging		Imaging	
Fetal		Р	Р	P		P	P	P	P	P	· · · · · · · · · · · · · · · · · · ·
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative											
(Specify)											
Intra-operative											
Neurological		<u> </u>	<u> </u>					<u> </u>			
Pediatric		<u> </u>	L					and the same			
Small Organ	ļ										
(Specify) *	ļ	<u></u>							ļ.,,	<u></u>	
Neonatal											
Cephalic											
Adult Cephalic											
Cardiac Transport	<u> </u>						<u> </u>		_		
Transesophageal								<u> </u>	7	<u> </u>	<u> </u>
Transrectal	<u> </u>					<u> </u>			<u> </u>		
Transvaginal Transurethral						· · · · · · · · · · · · · · · · · · ·			<u> </u>		
Intravascular						·			-		
Peripheral Vascular	-		-	<u></u>						<u> </u>	
Laparoscopic							<u> </u>	<u> </u>	<u> </u>		ļ <u>.</u>
Musculo-skeletal					·	·····	<u> </u>				ļ <u> </u>
Conventional								· ·		·	
Musculo-skeletal						in				<u></u> ,	ļ
Superficial	l · i										
Others (Specify)			-						-		
N= new indication;	P= p:	revio	usly	cleared	by FD.	A: E= adde	d under App	endiy F			
			•		•	-,		Olidia 2			
Other Indications or			T/D	OTEL CONT	VOTE: 55		· · · · · · · · · · · · · · · · · · ·	<u> </u>			_
** B/M, B/PWD, C *** Real time 3D	CIAT(1)/P\	ŵΩ,	rm(B	/CFM(M)			<u> </u>		-
Real time 3D			- :			· · · · · · · · · · · · · · · · · · ·			<u> </u>		_
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			<u> </u>	oncurrence	of CDRH	Office of Devi	ice Evaluation (OE	E)	cenen)		-

510(k) Number (if l Device Name : <u>Dia</u>	SOUI know ignos	nd E vn) : stic U	Devi	ce Ind Ko sound S	7128 ystem S	7			f <u>23</u> .		
Indications for use:	Dia	agno	stic u	ıltrasou		ging or Dop		of the huma	ın body as fo	llows:	
Clinical	A	В	М	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
Application					0,72	Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
Ophthalmic										11114651118	
Fetal		P	P	P		Р	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative							,		 		
(Specify)	ĺ										
Intra-operative											
Neurological			L	<u> </u>			İ				
Pediatric											<u> </u>
Small Organ]								····	
(Specify) *		<u> </u>			<u> </u>						
Neonatal]		_							
Cephalic		<u> </u>					ļ]
Adult Cephalic											
Cardiac											
Transesophageal						,					
Transrectal						,			<u> </u>		
Transvaginal											
Transurethral										- - 1	
Intravascular								· · · · · · · · · · · · · · · · · · ·			ļ
Peripheral Vascular		-,				, <u></u>		· · · · · · · · · · · · · · · · · · ·			
Laparoscopic											

Conventional				J		
Musculo-skeletal				•		
Superficial	_				1	
Others (Specify)						······································
N= new indication; P=	previously cl	eared by FDA: I	∛= added umde	r Annendiy F		
•		· · · · · · · · · · · · · · · · · · ·	s waasa unuo	rappoint D		
Other Indications or M	fodes:	•				
** B/M, B/PWD, CFM	(B)/PWD,CF	M(B)/CFM(M)	· · · · · · · · · · · · · · · · · · ·			
*** Real time 3D			·			
(PLE	ASE DO NOT WRI	TE BELOW THIS LIN	E-CONTINUE ON A	ANOTHER PAGE IF N	(EEDED)	
	Conc	surrence of CDRH, Off	ice of Device Evalua	tion (ODE)	, - , - 1 ,	

Musculo-skeletal

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number

Prescription	Use	(Per 21	CFR	801.	109)

Ultrasound Device Indications Statement Page 13 of 23.

510(k) Number (if known): _____K07128

Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA40R-035VPU</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mod	le of Opera	ition				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	<u> </u>	<u> </u>	<u>L</u>								-
Fetal		N	N	N		N	N	N	N	N	N
Abdominal		N	N	N	-	N	N	N	N	N	N
Intra-operative (Specify)											
Intra-operative											
Neurological Pediatric		<u> </u>					<u> </u>				
Small Organ (Specify) *											
Neonatal Cephalic										<u> </u>	
Adult Cephalic		-					l .			-	<u> </u>
Cardiac								····			
Transesophageal											
Transrectal								·	 		
Transvaginal								 	 	<u> </u>	
Transurethral									 		
Intravascular						,		·			
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal					-	·					
Conventional					ļ						
Musculo-skeletal Superficial											<u> </u>
Others (Specify)						" ,				<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHE Concurrence of CDRH, Office of Device Evaluation (ODI	R PAGE IF NEEDED)

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Division of Reproductive, Abdominal and

Radiological Devices

Indications for use:	TA	B .	M PWD	Mod	le of Opera	tion Power	Color	Combined	Tissue
Indications for use:									
	Diag	iagnosti	ic ultrasou	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:
Fill out or	e form	rm for e	each ultras	ound sy	stem or trai	nsducer.			
Device Name : <u>Di</u>	<u>ignost</u>	stic Ult	trasound S	ystem S	DU-2200P	ro, VA40R-0	<u>35VNU</u>		
510(k) Number (if			Ko.	7128	5].				
Ultra	soun	ınd De	evice Ind	ication	s Stateme	ent Page	e <u>14</u> o	f <u>23</u> .	
Prescription Use (I	er 21	l CFR	801.109)						
			,						

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic						······································	Зоррыя	.Timuging		imaging.	1
Fetal		N	N	N		N	N	N	N	N	N
Abdominal		N	N	N		N	N	N	N	N	N
Intra-operative (Specify)									***************************************		11
Intra-operative Neurological						·		·			
Pediatric									- 		
Small Organ (Specify) *											
Neonatal									 	·	
Cephalic		İ									
Adult Cephalic										 	
Cardiac -									+		
Transesophageal										 	
Transrectal									+		
Transvaginal								··		<u> </u>	
Transurethral											
Intravascular								 		<u> </u>	
Peripheral Vascular			7					· · · · · · · · · · · · · · · · · · ·			
Laparoscopic								<u></u>	1		
Musculo-skeletal Conventional								·		<u> </u>	
Musculo-skeletal Superficial						·			,		
Others (Specify)		_						<u> </u>			

Other Indications or Modes: ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) *** Real time 3D (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices KOTIA87

Prescription	Use	(Per	21	CFR	801	1091
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Ultrasound Device Indications Statement Page 15 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375WU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mog	le of Opera	tion				
Clinical Application	Ä	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	L										
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological			55.00			 					
Pediatric	Ĭ	1					**************************************		†···		
Small Organ (Specify) *								· · · · · · · · · · · · · · · · · · ·			
Neonatal				4-1							
Cephalic			l]				
Adult Cephalic											
Cardiac			J. 14			12.11	 		 		-
Transesophageal											
Transrectal											
Transvaginal	7 25		7		······	· · · · · · · · · · · · · · · · · · ·		 ,	 		
Transurethral			····					* **	1		
Intravascular		*			.1-4		 1255 wa ,		1		
Peripheral Vascular							 				
Laparoscopic	<u> </u>		-					······································			
Musculo-skeletal							 		 		
Conventional	ĺ).							
Musculo-skeletal Superficial				 				7			
Others (Specify)						···					

Other Indications or Modes:		
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)		·
*** Real time 3D	**************************************	
	#** · · · · · · · · · · · · · · · · · ·	
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Concurrence of CDRH, Office of Devi		

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Prescription	n Else	(Per 21	CFR	801	109)
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Ultrasound Device Indications Statement Page 16 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical М PWDColor Power ColorCombinedTissue Other Doppler(Amplitude) Velocity (Specify)** Application Harmonic (Specify) DopplerImaging Imaging Ophthalmic Fetal P P P P P Abdominal P P P P P P P Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal CephalicAdult Cephalic

Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
(PLEASE DO NOT WRITE BELOW THIS LINE-	CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDPH Office	of Device Fundamina (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Ultrasound Device Indications Statement

Page <u>17</u> of <u>23</u>.

510(k) Number (if known):

K071287

Device Name : Diagnostic Ultrasound System SDU-2200Pro, TV11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

						de of Opera	ation				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	ļ	<u> </u>	<u> </u>								
Fetal	<u> </u>	P	P	P		P	P	Р	P	P	
Abdominal			<u> </u>								1
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric									-		
Small Organ (Specify) *									-		
Neonatal				-	-						
Cephalic											
Adult Cephalic											
Cardiac										:-	
Transesophageal							1				<u> </u>
Transrectal		P	Р	P		P	P	P	P	Р	
Transvaginal		P	P	P		P	P	P	P	P	 -
Transurethral											<u> </u>
Intravascular									-		
Peripheral Vascular						· · · · · ·	· · · · · · · · · · · · · · · · · · ·		-		
Laparoscopic									 		
Musculo-skeletal									 		
Conventional											
Musculo-skeletal Superficial					7.7.	·		-		11	
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH Office of Device Find with CDDD	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

K07128

Clinical Application	A	В	·M	PWD	CWD	Color	Power (Amplitude)	Color	Combined	Tissue
					Mod	le of Opera	tion	_a +	6 64.1	
Indications for use:	Dia	ignos	stic u	ltrasou	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	nsducer.			
Device Name : Dia	gnos	tic L	ltras	ound S	ystem S	DU-2200P	ro, UB10R-0	65U		
510(k) Number (if)				<u>K</u> ı	5712	87				
Ultra	soui	ıd D)evi	ce Indi	ication	s Stateme	ent Page	e <u>18</u> c	of <u>23</u> .	
Prescription Use (P	er 21	CF	R 80	1.109)						

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic								Imaging	 	imaging	
Fetal			_							 	<u> </u>
Abdominal										··· <u></u>]
Intra-operative			i			· · · · · · · · · · · · · · · · · · ·	<u> </u>			<u> </u>	 -
(Specify)	ļ					,					
Intra-operative									 		
Neurological											
Pediatric							<u> </u>			· · · · · · · · · · · · · · · · · · ·	
Small Organ					_						
(Specify) *											
Neonatal							· · · · · · · · · · · · · · · · · · ·		 -	 : .	
Cephalic	L	Li									
Adult Cephalic							· · · · · ·				
Cardiac											
Transesophageal											
Transrectal		P	P	P		P	P	P	P	P	
Transvaginal											
Transurethral											·
Intravascular						-		<u> </u>	· · · · · · · · · · · · · · · · · · ·		
Peripheral Vascular								<u> </u>	· · · · · · · · · · · · · · · · · · ·		
Laparoscopic						······					
Musculo-skeletal								terior en la companya della companya		 	
Conventional				- [
Musculo-skeletal		\neg						<u> </u>			
Superficial											
Others (Specify)				+	<u> </u>	 -		<u> </u>			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

*** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

**** Real time 3D

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ultrasound Device Indications Statement

Page 19 of 23 .

510(k) Number (if known):

K071287

Device Name : Diagnostic Ultrasound System SDU-2200Pro, EC11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

<u> </u>		_				le of Opera	tion				_
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic		<u> </u>									
Fetal	<u> </u>	P	P	P		P	P	P	P	P	
Abdominal				1					-		
Intra-operative (Specify)										· · · · · · · · · · · · · · · · · · ·	
Intra-operative Neurological						-					
Pediatric										10 mg 1 mg 1 mg 1 mg 1 mg 1 mg 1 mg 1 mg	
Small Organ (Specify) *									-	·	
Neonatal											<u> </u>
Cephalic											
Adult Cephalic											
Cardiac									1		
Transesophageal									 		
Transrectal		P	P	P		P	P	P	P	P	
Transvaginal		P	P	P		P	P	P	P	P	
Transurethral									 		
Intravascular					" "		-				
Peripheral Vascular						·····			1		†
Laparoscopic									 	· · · · · · · · · · · · · · · · · · ·	
Musculo-skeletal											
Conventional]			ľ	
Musculo-skeletal					i.	. ,			<u> </u>		
Superficial			ļ	'							
Others (Specify)									 	 -	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:						
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)			<u>.</u>		**	
*** Real time 3D	· · · · · · · · · · · · · · · · · · ·	-		 :		
					· · · · · · · · · · · · · · · · · · ·	
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Concurrence of CDRH, Office	of Device Evaluation	n (ODE)				

Prescription	n Use	(Per 21	CER	201	100)
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Ultrasound Device Indications Statement P

Page 20 of 23.

510(k) Number (if known):

X011287

Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, EC10R-065VPU</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

r	,	<u> </u>	<u> </u>	=	Mod	le of Opera	ation				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic		<u> </u>	<u> </u>		l				<u> </u>		
Fetal		N	N	N		N	N	N	N	N	N
Abdominal									1	7	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric			Γ΄					-			
Small Organ (Specify) *								_		<u>. </u>	
Neonatal								.,	-		
Cephalic											
Adult Cephalic							<u> </u>		 		
Cardiac						 		-			
Transesophageal											
Transrectal		N	N	N		N	N	N	N	N	N
Transvaginal		N	N	N		N	N	N	N	N	N
Transurethral											
Intravascular										<u> </u>	•
Peripheral Vascular							 - - 		-		
Laparoscopic								·			
Musculo-skeletal				-		<u> </u>					
Conventional					•						
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	•	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)		
*** Real time 3D		
	·	· · · · · ·
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)		
Concurrence of CDRH, Office of Device Evaluation (ODE)		

Prescription Use (Per 21 CFR 801.109)				
Ultrasound Device Indications Statement	Page_	21	of_	23
510(k) Number (if known): K071287				
Device Name: Diagnostic Ultrasound System SDU-2200Pro, St	011-050U			

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude)	Color Velocity	Combined (Specify)**	Tissue Harmonic	Other (Specify)
Ophthalmic	 	-	<u> </u>			·	Doppler	Imaging		Imaging	***
Fetal	 	 	 				<u></u>			·	ļ
Abdominal	1		 	P		P	P			P	
Intra-operative	1	<u> </u>	\vdash			<u> </u>			<u> </u>	1	
(Specify)											
Intra-operative		· · ·							 	·	
Neurological											
Pediatric		P	P	P	P	P	P	P	P	P	
Small Organ (Specify) *								· · · · · · · · · · · · · · · · · · ·			
Neonatal			-					<u></u>	 -		
Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	Р	P	P	
Transesophageal		L									
Transrectal											
Transvaginal											
Transurethral											
Intravascular									* -		
Peripheral Vascular										-	
Laparoscopic											†
Musculo-skeletal											
Conventional											
Musculo-skeletal											
Superficial	Ш			·							
Others (Specify)		L i				<u>. </u>					

Other Indications or Modes:		
** B/M, B/PWD, CFM(B)/PW	VD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD	•
Harmonic Imaging		
*** Real time 3D		
(PLEASE DO N	OT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
	Concurrence of CDRH, Office of Device Evaluation (ODE)	

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices Ko71287
510(k) Number

Ultrasound Device Indications Statement

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510(k) Number (if known):

K671287

Device Name: Diagnostic Ultrasound System SDU-2200Pro, S017-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mod	le of Opera	ition				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	ļ	ļ	<u> </u>								
Fetal	ļ										
Abdominal				Р		P	P			Р	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric]								
Small Organ (Specify) *											
Neonatal Cephalic									· · · · · · · · ·	-	
Adult Cephalic		_									
Cardiac		P	P	P	P	P	P	P	P	P	
Transesophageal							 		 -		<u> </u>
Transrectal											
Transvaginal										::.	
Transurethral								·			
Intravascular											
Peripheral Vascular										<u></u>	
Laparoscopic								: -	<u> </u>		
Musculo-skeletal Conventional											 ,
Musculo-skeletal Superficial									<u> </u>		
Others (Specify)					-	- :	- -				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD	_
Harmonic Imaging	-
*** Real time 3D	_
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Concurrence of CDRH Office of Device Englishing (ODC)	_

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number _

K07128

Ultrasound Device Indications Statement Page 23 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-2200Pro, S020-025U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mod	le of Opera	ation				
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic						·					
Fetal	<u> </u>	<u> </u>	<u> </u>								
Abdominal				P		P	P		,	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric									_	·	
Small Organ (Specify) *			,	-				· · · · · · · · · · · · · · · · · · ·		,, <u> </u>	
Neonatal											
Cephalic						· 					
Adult Cephalic											
Cardiac		P	P	P	P	P	P	P	P	P	
Transesophageal									T		
Transrectal											
Transvaginal											<u> </u>
Transurethral											
Intravascular	<u> </u>										
Peripheral Vascular											
Laparoscopic											†
Musculo-skeletal									-		
Conventional											
Musculo-skeletal Superficial											
Others (Specify)				· -						<u></u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD	_
Harmonic Imaging	_
*** Real time 3D	_
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Concurrence of CDRH, Office of Device Evaluation (ODE)	_

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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number